

### REMARKS

Applicant respectfully requests reconsideration of this application as amended.

As a preliminary matter, in the Office Actions mailed September 21, 2004 and June 15, 2005, the Examiner did not attach an initialed copy of the PTO-1449 form references that were mailed to the PTO on September 4, 2004. As such, applicant respectfully requests that the Examiner indicate that these references have been considered and made of record. The Examiner also did not indicate the references on the PTO-1449 form(s) were not in conformance with MPEP 609. As such, applicant respectfully requests that the Examiner indicate that these references have been considered and made of record.

#### Office Action Rejections Summary

Claims 1-29 have been rejected under 35 U.S.C. §101.

Claims 1-29 have been rejected under 35 U.S.C. §112, first paragraph.

Claims 1-3, 7-19, and 23-29 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,371,904 of Sirimanne et al. (hereinafter "Sirimanne") in view of U.S. Patent Application Publication No. 2004/0024304 of Foerster et al. (hereinafter "Foerster").

Claims 4-6 and 20-22 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Sirimanne in view of Foerster and further in view of U.S. Patent No. 5,562,641 of Flomenblit et al. (hereinafter "Flomenblit").

No claims have been allowed.

### Status of Amendments

Claims 1-29 have been canceled. Claims 30-65 have been added. The new claims are supported by the specification. No new matter has been added.

The specification has been amended to correct minor matters of form. No new matter has been added.

The drawings have not been amended.

### Claim Rejections under 35 U.S.C. § 101

Claims 1-29 stand rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter because they inferentially claim the human body.

However claims 1-29 have been canceled. Therefore, this rejection is moot.

Applicant respectfully asserts that the new claims 30-65 are not directed to non-statutory subject matter and, therefore, are not subject to rejection under 35 U.S.C. § 101. In particular, the method claims 30-35, 46-51, and 61-65 refer to a tissue target area and/or a target area of a patient, but do not inferentially claim humans. The apparatus claims 36-45 and 57-60 do not refer to tissue or humans. The apparatus claims 52-56 are written with functional language under 35 U.S.C. § 112, sixth paragraph, and consequently does not inferentially claim humans.

Given that none of the independent claims are directed to non-statutory subject matter, the previous rejection under 35 U.S.C. § 101 is not applicable to the new claims.

### Claim Rejections under 35 U.S.C. § 112, First Paragraph

Claims 1-29 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement because the limitation of

“non-void” is purportedly new matter. Although Applicant respectfully submits that the limitation “non-void” is not new matter because it is supported by the specification, this rejection is moot because the new claims 30-65 do not include the disputed language.

Claim Rejections under 35 U.S.C. § 103(a)

Claims 1-29 stand rejected under 35 U.S.C. § 103(a). In particular, claims 1-3, 7-19, and 23-29 stand rejected as being unpatentable over Sirimanne in view of Foester. Claims 4-6 and 20-22 stand rejected as being unpatentable over Sirimanne in view of Foester and further in view of Flomenblit. However, claims 1-29 have been canceled. Therefore, the rejection of claims 1-29 under 35 U.S.C. § 103(a) is moot. Applicant respectfully submits that the new claims are patentable over the cited references because the references, either individually or in combination, do not teach or suggest all the limitations of the claimed invention.

CLAIMS 30-35

With regard to claims 30-35, the combination of cited references fails to teach or suggest every limitation of independent claim 30. Claim 30 recites:

A method, comprising:

depositing a fiducial into a target region of a patient;  
detecting the fiducial using electromagnetic radiation to  
locate the target region of the patient; and  
**performing stereotaxic radiosurgery** on the target region of  
the patient according to the detected fiducial and the location of the  
target region.

(Emphasis added.)

Sirimanne is directed to a marking device that may be inserted into a subcutaneous cavity to expand within the cavity and mark the cavity.

Sirimanne, Abstract. The marker enables someone to determine the location,

orientation, and periphery of the cavity. Sirimanne, col. 1, lines 10-17. However, Sirimanne does not teach or suggest use of its maker for “performing stereotaxic radiosurgery,” as recited in claim 30.

Foerster is directed to a permanent identification marker. Foerster, Abstract. Foerster teaches visualizing the marker, using an imaging system, for diagnostic or therapeutic procedures. Foerster, ¶ 0016. However, Foerster does not teach or suggest use of its marker for “performing stereotaxic radiosurgery,” as recited in claim 30. Furthermore, the combination of Sirimanne and Foerster does not teach or suggest “performing stereotaxic radiosurgery,” as recited in claim 30.

Accordingly, the cited references, either alone or in combination, do not teach or suggest “performing stereotaxic radiosurgery,” as recited in claim 30. Therefore, Applicant respectfully submits that claim 30 is patentable over the combination of references.

Given that the cited references do not teach or suggest all of the limitations of independent claim 30, Applicant submits that claims 31-35, which depend from claim 30, are also patentable over the cited references.

#### CLAIMS 36-45

With regard to claims 36-45, the combination of cited references fails to teach or suggest every limitation of independent claim 36. Claim 36 recites:

A fiducial apparatus, comprising:  
a **body portion having a housing**, the body portion comprising a material visible using electromagnetic radiation; and  
an anchor member coupled to the body portion, the anchor member having an unanchored position and an anchored position, **the anchor member drawn into the housing in the unanchored position and withdrawn from the housing in the anchored position.**

(Emphasis added.)

Sirimanne is directed to a marking device that may be inserted into a subcutaneous cavity to expand within the cavity and mark the cavity. Sirimanne, Abstract. The marking device includes a body and a marker. Sirimanne, col. 7, lines 1-31. Sirimanne teaches several types of bodies and markers, such as a spherical body 102 and a centrally located mark 150 (Sirimanne, col. 7, lines 26-43) and a substantially spherical body 158 made of suture material looped through a marker 154 (Sirimanne, col. 9, lines 34-51). Furthermore, Sirimanne teaches that the body anchors the marking device, including the body and marker, within the cavity. Sirimanne, col. 5, lines 4-20. Therefore, the body anchors itself, along with the marker, within the cavity. Given that the body is also the anchoring mechanism, it would not be reasonable to assert that the body has a housing that houses itself as the anchor. Accordingly, Sirimanne does not teach or suggest the body having a housing of any sort and, in particular, a housing that houses an anchor member.

Foerster is directed to a permanent identification marker. Foerster, Abstract. Foerster teaches several types of marker elements, including an umbrella end with wings and a center wire (Foerster, ¶ 0041), a "U" shaped clip (Foerster, ¶ 0055), and several compression springs. The marker elements taught by Foerster do not have a housing for an anchor member. The marker element of Foerster is simply an elastic metal member that decompresses once released from the injection device. Accordingly, Foerster does not teach or suggest the marker element having a housing for an anchor member.

In contrast, claim 36 recites "body portion having a housing" with the "anchor member drawn into the housing in the unanchored position and withdrawn from the housing in the anchored position." Therefore, the cited references do not render claim 36 obvious because the cited references, either

alone or in combination, do not teach or suggest a “body portion having a housing” with the “anchor member drawn into the housing in the unanchored position and withdrawn from the housing in the anchored position,” as recited in claim 36. Therefore, Applicant respectfully submits that claim 36 is patentable over the combination of references.

Given that the cited references do not teach or suggest all of the limitations of independent claim 36, Applicant submits that claims 37-45, which depend from claim 36, are also patentable over the cited references.

#### CLAIMS 46-51

With regard to claims 46-51, the combination of cited references fails to teach or suggest every limitation of independent claim 46. Claim 46 recites:

A method, comprising:

inserting an insertion needle into a tissue target region of a patient, the insertion needle containing a fiducial in an unanchored position, the fiducial comprising a body portion and an anchor member coupled to the body portion, the **body portion having a housing, the anchor member drawn into the housing in the unanchored position;**

displacing a portion of the tissue target region; and  
depositing the fiducial into the tissue target region, the **anchor member withdrawing from the housing** and embedding in the tissue target region in response to the fiducial exiting the insertion needle.

(Emphasis added.)

Sirimanne is directed to a marking device that may be inserted into a subcutaneous cavity to expand within the cavity and mark the cavity.

Sirimanne, Abstract. The marking device includes a body and a marker. Given that the body is also the anchoring mechanism, Sirimanne does not teach or suggest the body having a housing of any sort and, in particular, a housing that houses an anchor member.

Foerster is directed to a permanent identification marker. Foerster, Abstract. Foerster teaches several types of marker elements. Generally, the marker element of Foerster is simply an elastic metal member that decompresses once released from the injection device. Accordingly, Foerster does not teach or suggest the marker element having a housing for an anchor member.

In contrast, claim 46 recites a "body portion having a housing" with the "anchor member drawn into the housing in the unanchored position" and the "anchor member withdrawing from the housing." Accordingly, the cited references, either alone or in combination, do not teach or suggest a "body portion having a housing" with the "anchor member drawn into the housing in the unanchored position" and the "anchor member withdrawing from the housing," as recited in claim 46. Therefore, Applicant respectfully submits that claim 46 is patentable over the combination of references.

Given that the cited references do not teach or suggest all of the limitations of independent claim 46, Applicant submits that claims 47-51, which depend from claim 46, are also patentable over the cited references.

#### CLAIMS 52-56

With regard to claims 52-56, the combination of cited references fails to teach or suggest every limitation of independent claim 52. Claim 52 recites:

A fiducial apparatus, comprising:

means for coupling an anchor member to a body portion, the **body portion having a housing, the anchor member drawn into the housing in an unanchored position;**

means for displacing a portion of a tissue target region; and

means for embedding the anchor member in the tissue target region.

(Emphasis added.)

Sirimanne is directed to a marking device that may be inserted into a subcutaneous cavity to expand within the cavity and mark the cavity. Sirimanne, Abstract. The marking device includes a body and a marker. Given that the body is also the anchoring mechanism, Sirimanne does not teach or suggest the body having a housing of any sort and, in particular, a housing that houses an anchor member.

Foerster is directed to a permanent identification marker. Foerster, Abstract. Foerster teaches several types of marker elements. Generally, the marker element of Foerster is simply an elastic metal member that decompresses once released from the injection device. Accordingly, Foerster does not teach or suggest the marker element having a housing for an anchor member.

In contrast, claim 52 recites a “body portion having a housing” with the “anchor member drawn into the housing in an unanchored position.” Accordingly, the cited references, either alone or in combination, do not teach or suggest a “body portion having a housing” with the “anchor member drawn into the housing in an unanchored position,” as recited in claim 52. Therefore, Applicant respectfully submits that claim 52 is patentable over the combination of references.

Given that the cited references do not teach or suggest all of the limitations of independent claim 52, Applicant submits that claims 53-56, which depend from claim 52, are also patentable over the cited references.



## CLAIMS 57-60

With regard to claims 57-60, the combination of cited references fails to teach or suggest every limitation of independent claim 57. Claim 57 recites:

A fiducial apparatus, comprising:  
an elastic body portion having an unanchored position and an anchored position, the **elastic body portion expandable to receive a material in an internal cavity** in the anchored position, the material visible using electromagnetic radiation; and  
a lumen coupled to the elastic body portion to provide a channel for the material to enter the internal cavity of the elastic body portion.

(Emphasis added.)

Sirimanne is directed to a marking device that may be inserted into a subcutaneous cavity to expand within the cavity and mark the cavity.

Sirimanne, Abstract. The marking device includes a body and a marker.

Sirimanne, col. 7, lines 1-31. Although Sirimanne teaches several types of bodies and markers, Sirimanne does not teach or suggest an “elastic body portion expandable to receive a material in an internal cavity,” as recited in claim 57.

Foerster is directed to a permanent identification marker. Foerster, Abstract. Foerster teaches several types of marker elements, including several elastic spring-like markers, but does not teach or suggest an “elastic body portion expandable to receive a material in an internal cavity,” as recited in claim 57.

Accordingly, the cited references, either alone or in combination, do not teach or suggest an “elastic body portion expandable to receive a material in an internal cavity,” as recited in claim 57. Therefore, Applicant respectfully submits that claim 57 is patentable over the combination of references.

Given that the cited references do not teach or suggest all of the limitations of independent claim 57, Applicant submits that claims 58-60, which depend from claim 57, are also patentable over the cited references.

#### CLAIMS 61-65

With regard to claims 61-65, the combination of cited references fails to teach or suggest every limitation of independent claim 57. Claim 57 recites:

A method, comprising:  
    inserting a fiducial in an unanchored position into a target tissue region, the fiducial comprising **an elastic body portion defining an internal cavity**;  
    displacing a portion of the tissue target region; and  
    **depositing a material into the internal cavity** of the elastic body portion to expand and anchor the elastic body portion within the tissue target region, the material visible using electromagnetic radiation.

(Emphasis added.)

Sirimanne is directed to a marking device that may be inserted into a subcutaneous cavity to expand within the cavity and mark the cavity.

Sirimanne, Abstract. The marking device includes a body and a marker.

Sirimanne, col. 7, lines 1-31. Although Sirimanne teaches several types of bodies and markers, Sirimanne does not teach or suggest “an elastic body portion defining an internal cavity” and “depositing a material into the internal cavity,” as recited in claim 61.

Foerster is directed to a permanent identification marker. Foerster, Abstract. Foerster teaches several types of marker elements, including several elastic spring-like markers, but does not teach or suggest “an elastic body portion defining an internal cavity” and “depositing a material into the internal cavity,” as recited in claim 61.

Accordingly, the cited references, either alone or in combination, do not teach or suggest "an elastic body portion defining an internal cavity" and "depositing a material into the internal cavity," as recited in claim 61. Therefore, Applicant respectfully submits that claim 61 is patentable over the combination of references.

Given that the cited references do not teach or suggest all of the limitations of independent claim 61, Applicant submits that claims 62-65, which depend from claim 61, are also patentable over the cited references.

### CONCLUSION

In conclusion, applicants respectfully submit that in view of the arguments and amendments set forth herein, the applicable rejections are moot or have been overcome.

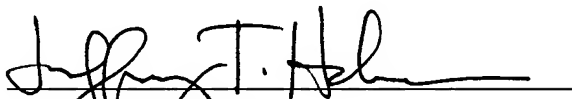
If the Examiner believes a telephone interview would expedite the prosecution of this application, the Examiner is invited to contact Jeffrey Holman at (408) 720-8300.

If there are any additional charges, please charge our Deposit Account No. 02-2666.

Respectfully submitted,

BLAKELY, SOKOLOFF, TAYLOR & ZAFMAN LLP

Dated: September 15, 2005

  
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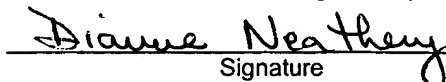
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